PATENT COOPERATION TREATY

Batya

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)
(PCT Rule 44bis.1(c))

To:

FENSTER, Paul
Fenster & Company Intellectual Property Ltd.
P.O. Box 10256
Petach Tikva 49002
ISRAËL

Date of mailing *(day/month/year)* 31 December 2008 (31.12.2008)	
Applicant's or agent's file reference 372/04723	**IMPORTANT NOTICE**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2005/000131	03 February 2005 (03.02.2005)	03 February 2004 (03.02.2004)

Applicant
ATRIA MEDICAL INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 372/04723	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/IL2005/000131	International filing date *(day/month/year)* 03 February 2005 (03.02.2005)	Priority date *(day/month/year)* 03 February 2004 (03.02.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ATRIA MEDICAL INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 16 December 2008 (16.12.2008)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Simin Baharlou e-mail: pt09.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
EITAN, PEARL, LATZER & COHEN-ZEDEK
7 SHENKAR STREET
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	07 APR 2008
Applicant's or agent's file reference P-6765-PC	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL05/00131	03 February 2005 (03.02.2005)	03 February 2004 (03.02.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC: **A61M 5/00**(2006.01) A61M 1/10(2006.01);A61F 2/24(2006.01)
USPC: 604/8,9;623/2.1,3.1

Applicant

ATRIA MEDICAL INC.

1. This opinion contains indications relating to the following items:

- [X] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [X] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [ ] Box No. VII — Certain defects in the international application
- [ ] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	24 March 2008 (24.03.2008)	Tatyana Zalukaeva Telephone No. (571) 272-3235

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL05/00131

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL05/00131

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1-27	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-27	NO
Industrial applicability (IA)	Claims 1-27	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-27 lack novelty under PCT Article 33(2) as being anticipated by Alferness et al. (US 2004/016514). Alferness discloses a differential pressure regulating device comprising a shunt that is positioned between the left atrium and right atrium of the heart. The device comprises a flow-regulating valve that adjusts to regulate pressure between the atria based on a pressure threshold. The device is implant in the atrial septum, such that it establishes fluid communication between the atria.

Claims 1-6, 9-12, and 15-22 lack novelty under PCT Article 33(2) as being anticipated by Wolf et al. (US 6,641,610). Wolf discloses a device for regulating pressure between two lumens in the heart. An adjustable valve is disposed in the lumen to selectively cover the opening and regulate the flow of fluid through the shunt. A control mechanism (30) is coupled to the valve to remotely activate the valve. The shunt continuously regulates the pressure between the two lumens of the heart.

Claims 7, 8, 13, 14, and 23-27 lack an inventive step under PCT Article 33(3) as being obvious over Wolf et al. (US 6,641,610). Wolf, however, does not explicitly state that shunt is implanted in the interatrial septum, between the right and left atria. Wilk, however, suggests that the implant may be used to regulate flow between and chambers of the heart, and may be used on any heart wall, including the interatrial septum (see Column 3, Line 25 through Column 4 Line 18). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to place the flow and pressure regulating shunt of Wolf in the interatrial septum, such that pressure-regulated bypass from one atrium ot the other may be established.